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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,344	03/26/2001	John Richard Baker	441842000401	1139

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,344

Applicant(s)

BAKER, JOHN RICHARD

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-35 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-35 and 37-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4/25/03. 6) ☐ Other: _____

DETAILED ACTION

Claims 27-35, 37-40 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 27-35, 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please see the discussion below under “Response to Applicant’s Arguments”. In short, neither the enzyme, the substrates nor the products appear to be properly named or properly structurally depicted. The language of the claims and the disclosure in Figure 1 do not correspond to a known chemical terminology or manner of depicting the structures of the elements in the claims. Thus, the claims are unclear as interpreted in light of the specification as to the metes and bounds of the assay.

In claims 28 and 29, it is unclear what applicant means by “superoxide reaction product” or “oxygen free radical reaction product”. Are these intended to be products of the reaction? In Figure 1, the products of the reaction appear to be enzyme-NHR and α -dicarbonyl. Thus, the product of the reaction catalyzed by “fructosamine oxidase” according to Figure 1 does not appear to be superoxide.

Claim 30, where is the mechanism disabled? The claim appears to be missing some connecting elements and is not clear.

Claim Rejections – 35 USC § 102

Claims 27-29, 34 and 35 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Horiuchi *et al.* [46].

The claims are directed to a method of assaying fructosamine oxidase activity comprising measuring the conversion of a substrate to a product catalyzed by fructosamine oxidase. This encompasses measuring either the disappearance of a substrate or the appearance of a product.

The references are relied upon as explained below.

Horiuchi *et al.* disclose a method of assaying fructosyl-amino acid oxidase (E.C. 1.5.3) comprising: adding fructosyl-glycine to the oxidase in a buffer at pH 8 (p.104, Enzyme assay) and measuring glycine and glycosone and hydrogen peroxide, the products of the reaction, see Table II or measuring the disappearance of oxygen, a substrate of the reaction.

Claims 28 and 29 recite that the conversion is measured by determining a level of superoxide reaction product/oxygen free radical product. Since hydrogen peroxide is considered to be both a superoxide reaction product and an oxygen free radical reaction product, the reference is considered to meet the limitations of the claim.

Response to Arguments

Applicant's arguments filed 11/10/03 have been fully considered but they are not persuasive.

Applicant argues that the enzyme taught by Hourichi *et al.* is different from the instant enzyme because the names are different. The naming of an enzyme is not always a perfect exercise and depends on the chemical expertise of the namer. What distinguishes an enzyme is its activity not its name. In this regard, applicant argues that the instant substrate is fructosamine while the substrate of the prior art is fructosyl-glycine. However, an amine has the structure of $-NH_2$ while the instant substrate pictured in figure 1 has a fructose bound to an amino acid or protein through a terminal amine group of the protein moiety. Fructosamine is not the proper name for such a construct. And further, the sugar diagrammed in Figure 1 is not even fructose. Thus, applicant's scientifically incorrect arguments based on improper nomenclature and confusing and inaccurate diagrams are not persuasive. See attached CA Registry number 4420-04-3 for the proper structure of the compound, fructosylamine.

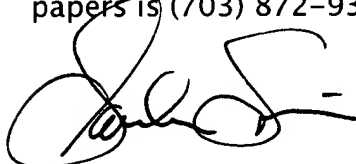
Also, applicant argues that the product of the instant reaction is different from the product of the disclosed reaction in that the product of the instant reaction is an α -dicarbonyl and the product of Hourichi *et al.* is a glucosone. Please note that a glucosone is also known as a fructosone and may be the same as applicant's " α -dicarbonyl" which is also not correctly diagrammed and in addition appears to be misnamed. See CA Registry number 1854-25-7 attached. Applicant also appears to misinterpret the reference with regard to the presence of a carbonyl group in fructose.

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In the classic representations of monosaccharides, the carbonyl group is clearly depicted see CA REGISTRY number 1854-25-7. Applicant has unsuccessfully attempted to write the chemical formula in the chair form of a pyranose ring and so the carbonyl group which forms part of the chain in this convention is not so clearly depicted as in the classical representations of saccharides. It is unclear what the claimed reaction is in terms of both enzyme, substrates and products formed because of inaccurate nomenclature and depiction of structures.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.



Sandra Saucier
Primary Examiner
Art Unit 1651
January 2, 2004